

Santen Files for Manufacturing and Marketing Approval of STN1008903 (diquafosol sodium) - Improved formulation to reduce the frequency of administration to ease patients' burden -

August 30, 2021, Osaka, Japan - Santen Pharmaceutical Co., Ltd. (Head office in Osaka; hereinafter "Santen") announced today the filing for manufacturing and marketing approval of dry eye ophthalmic drug STN1008903 (diquafosol sodium) in Japan.

STN1008903 is a formulation developed for the purpose of reducing the frequency of administration, an improvement over the current product *DIQUAS Ophthalmic Solution 3%*, which was launched in Japan in 2010 and has the dose of one drop at a time, six times a day. One of the factors that contribute to reduced medication adherence is the difficulty and hassle of taking medication. With this situation, Santen has developed a formulation that requires fewer applications while maintaining the efficacy and safety of the *DIQUAS Ophthalmic Solution 3%*, a recommended treatment for dry eye*¹. The new candidate meets unmet clinical needs and is expected to contribute to easing patients' burden associated with eye drop application.

STN1008903's active ingredient, diquafosol sodium, is a P2Y₂ receptor agonist that acts on conjunctival tissues to promote the secretion of tears containing water and mucins. It also has the effect of promoting the expression and secretion of membrane-bound mucins on corneal epithelium, thereby quantitatively and qualitatively improving tear abnormalities and bringing the ocular surface to a normal condition to demonstrate a clinically significant efficacy.

The efficacy of STN1008903 in patients with dry eye was examined in Phase III clinical trial in Japan (randomized, double-masked, placebo-controlled, parallel-group, multicenter study)*². The study demonstrated that STN1008903 is superior to placebo eye drops in the level (score) of corneal epithelial staining from fluorescein, confirming its ability to improve corneal and conjunctival epithelial disorders. No serious ocular or systemic side effects have been observed.

As a specialized company dedicated to ophthalmology, we are committed to reducing the loss of social and economic opportunities for people around the world due to eye conditions. We are also enhance the level of convenience in treatments to improve medication compliance, thereby contributing to raising QOL (quality of life) for patients.

*¹ Source: Dry Eye Clinical Practice Guidelines (Japan)

https://www.nichigan.or.jp/Portals/0/resources/member/guideline/dryeye_guideline.pdf

*² Clinical Trials Information Registration Number (JapicCTI-205177), Japan Pharmaceutical Information Center (Japan)

<https://www.clinicaltrials.jp/cti-user/trial/ShowDirect.jsp?japicid=JapicCTI-205177>

About DIQUAS Ophthalmic Solution 3% (diquafosol sodium)

DIQUAS Ophthalmic Solution 3% is an ophthalmic solution licensed from Inspire Pharmaceuticals, Inc. (U.S.A) and developed by Santen for dry eye treatment. In April 2010, Santen was received approval for manufacturing and marketing authorization as a dry eye treatment in Japan (indication / efficacy: dry eye, application / dosage: one drop at a time, six times a day). The product has also received marketing approval in China, South Korea and other Asian countries, and is currently used as a dry eye treatment widely.

About Santen

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices, and its products now reach patients in over 60 countries.

Toward realizing “WORLD VISION” (Happiness with Vision), the world Santen ultimately aspires to achieve, as a “Social Innovator”, we aim to reduce the social and economic opportunity loss of people around the world caused by eye diseases and defects by orchestrating and mobilizing key technologies and players around the world.

With scientific knowledge and organizational capabilities nurtured over a 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen’s website (www.santen.com).

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